K062306

8.0 Premarket Notification 510(k) Summary
[As required by section 807.92(c)]

MAR 16 2007

Applicant:

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USA

Contact:

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Date:

July 24, 2006

Trade Name:

R2 Diagnostics PlasmaCon N,
PlasmaCon L-1,
PlasmaCon L-2

Common Name:

Controls, Plasma, Normal and Abnormal for Coagulation

Classification Name:

Control, Plasma, Normal and Abnormal (per 21 CFR section 864.5425)

Comparison Device:

Normal Coagulation Control Plasma K895262
Abnormal Coagulation Control Plasma Level-1 K895260
Abnormal Coagulation Control Plasma Level-2 K895261

Description of the Device

The PlasmaCon Control Plasma devices contain lyophilized citrated human plasma, for use in the verification of system performance for PT and aPTT assays. The PlasmaCon Control plasmas should only be used in an appropriate clinical laboratory by qualified laboratory professionals. The tests may be performed manually, or using semi-automated and automated coagulation analyzers.

Statement of the Intended Use
PlasmaCon N is a human lyophilized plasma control intended for use as a normal control with citrated plasma to monitor the performance of the Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) tests.

PlasmaCon L-1 is a human lyophilized plasma control intended for use as a mid-level abnormal control with citrated plasma to monitor the performance of the Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) tests.

PlasmaCon L-2 is a human lyophilized plasma control intended for use as a high level abnormal control with citrated plasma to monitor the performance of the Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) tests.

Summary of Substantial Equivalence Comparisons
R2 Diagnostics' PlasmaCon Control Plasmas are substantially equivalent in intended use and performance to Normal and Abnormal Control Plasma devices currently marketed by Trinity Biotech. Both the predicate device and the proposed product for in vitro diagnostic use in routine patient screening tests. Both are formulated from citrated human plasma.

Precision studies were performed to establish Within Run and Between Run CVs according to the following procedure developed under NCCLS EP-15A: User Demonstration of Performance for Precision and Accuracy; Approved Guidelines. For within run, 10 vials of each sample were pooled, tested, and recorded in duplicate or triplicate. For between run, 2 vials of each sample were pooled, tested in duplicate, and recorded each day for 5 days.

In comparison studies normal and abnormal control plasma controls were tested using PT and aPTT reagents from multiple manufacturers on multiple instrument types to include:

- r^2 Diagnostics Phospholin ES on the ACL3000+, MLA1000c and ACL Advance.
- r^2 Diagnostics Phosphoplastin RL on the ACL3000+, MLA1000c and ACL Advance.
- Dade-Behring Thromborel S on the Dade BCS.
- Dade-Behring Pathromtin SL on the Dade BCS.
- Stago Neoplastine CI+ on the Stago STA.
- Stago Auto PTT on the Stago STA.

Within-run and between-run precision studies were performed and CV's of less than 15% were obtained for the proposed device. CV's of less than 15% are reported for the predicate device in this study.

Conclusion: Substantial Equivalence Statement

In Summary, the similar intended use, technological characteristics and the performance data provided in this premarket notification demonstrate that R2 PlasmaCon N, PlasmaCon L-1, and PlasmaCon L-2 are substantially equivalent to (Trinity Biotech) Medical Diagnostic Technologies, Normal Coagulation Control Plasma, Abnormal Coagulation Control Plasma 1, and Abnormal Coagulation Control Plasma 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

R2 DIAGNOSTICS, INC.
C/O Kara M. Young
1801 Commerce Drive
South Bend, Indiana 46628

MAR 16 2007

Re: k062306
Trade/Device Name: PlasmaCon N, PlasmaCon L-1, PlasmaCon L-2
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System For In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: GIZ, GGC
Dated: July 24, 2006
Received: August 8, 2006

Dear Ms. Young:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

6.0 Indications for Use

510(k) Number (if known): K 062306

Device Name: PlasmaCon N

Indications for Use:

Statement of Indications for Use

PlasmaCon N is a human lyophilized plasma control intended for use as a normal control with citrated plasma to monitor the performance of the prothrombin time (PT) and activated partial thromboplastin time (aPTT) tests.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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(Posted November 13, 2003) 510(k) K062306

510(k) Number (if known): K 062306

Device Name: PlasmaCon L-1

Indications for Use:

Statement of Indications for Use

PlasmaCon L-1 is a human lyophilized plasma control intended for use as a mid-level abnormal control with citrated plasma to monitor the performance of the prothrombin time (PT) and activated partial thromboplastin time (aPTT) tests.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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(Posted November 13, 2003) 510(k) K062306

510(k) Number (if known): K 062306

Device Name: PlasmaCon L-2

Indications for Use:

Statement of Indications for Use

PlasmaCon L-2 is a human lyophilized plasma control intended for use as a high level abnormal control with citrated plasma to monitor the performance of the prothrombin time (PT) and activated partial thromboplastin time (aPTT) tests.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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